AOS

Alpha-Omega Services, Inc.

December 6, 2010

ATTN: Document Control Desk
Director, Spent Fuel Project Office
Office of Nuclear Material Safety and Safeguards
U.S. Nuclear Regulatory Commission
Washington, DC 20555-0001

Subject: Application for review - quality assurance program approval for radioactive material packages

Reference: No. 0086, Revision 8
Docket No. 71-0086

Please find enclosed a review copy of the Alpha-Omega Services, Inc. Quality Assurance Program – Radioactive Material Transport Packages, proposed Revision D.

Submittal of this document is to satisfy the requirements of Regulatory Guide 7.10 Revision 2 (03-2005) for review and approval by the NRC of the proposed revisions to a quality assurance program description meeting the requirements of 10CFR Part 71 Subpart H – *Quality Assurance*; prior to its implementation. Approval of the document would satisfy the requirements of 10CFR 71.17(b) and 71.101(f).

After approval from the NRC is received, the Date of Implementation found on the QA Program Cover Page will be indicated; and this revision will then be effective.

All correspondence relative to this application for review shall be sent to:

Mr. Troy Hedger, President
Alpha-Omega Services, Inc.
9156 Rose Street
Bellflower, CA 90706

Sincerely

Alpha-Omega Services, Inc.

Paul D. Watts

Quality Assurance

Enclosure: AOS Quality Assurance Program – Radioactive Material Transport Packages, proposed Revision D document

Copy to: FM0018-112010-001 File

Q004

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PR9000

Revision D

QUALITY ASSURANCE PROGRAM

Radioactive Material Transport Packages

Date of Implementation: xx-xx-xxxx

Revision	***D***					
FM No.	***FM0018-112010-001***					

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Quality Assurance Program – Radioactive Material Transport Packages

POLICY STATEMENT

Alpha-Omega Services, Inc. (AOS) is engaged in the design, procurement, fabrication, assembly, testing, modification, maintenance, repair, and use of radioactive material transportation package activities that are safety-related or important-to-safety; and has the responsibility to protect the health and safety of the public and its employees. AOS has established a Quality Assurance Program (QA Program) for Radioactive Material Transport Packages (packages) designed to comply with the requirements of 10CFR71 Subpart H; and the program is reviewed and approved by the USNRC prior to implementation.

The management of AOS recognizes that the Quality Assurance personnel performing functions affecting quality are to be independent of all other functions. The administrator of Quality Assurance has been given the full authority and responsibility for establishing and maintaining the QA Program and implementing procedures; and for the control, administration and enforcement of all sections to obtain full compliance with the QA Program. The administrator of Quality Assurance has the organizational freedom to identify quality problems; initiate, recommend, or provide solutions; verify implementations of solutions; and to limit or control further processing, or delivery of a nonconforming item or unsatisfactory condition until proper disposition has occurred.

The President of AOS retains the overall authority and responsibility for the implementation of the Quality Assurance Program; and expects each and every employee to assume responsibility for performing their assigned work activities in accordance with its established requirements and policies. The Program ensures that quality is achieved and maintained by those assigned responsibility for performing work; with achievement verified and documented by persons or organizations not directly responsible for performing the work.

When problems or differences of opinion on quality issues cannot be resolved through normal lines of communication, these issues are to be brought to the attention of the President for resolution. Resolution shall always result in compliance with the applicable code, contract, and/or regulatory requirements as required.

The management of AOS is firmly committed to the requirements of this QA Program; and total participation of all personnel that represent this company is required.

Troy Hedger, President
Alpha-Omega Services, Inc.

1.0 ORGANIZATION AND RESPONSIBILITY

1.1 General organization and responsibilities for the establishment and implementation of the Quality Assurance Program (QA Program) are defined and documented - including functional responsibilities, levels of authority, and lines of communication for activities that affect quality; and are described in detail by the implementing procedures.

1.2 **Section 20.0, *Organizational Chart***; indicates organizational positions with primary responsibility to the quality activities as described in the QA Program.

1.3 The President of AOS retains the overall authority and responsibility for the implementation of the Quality Assurance Program identified in the Policy Statement; and is responsible for the desired end result.

1.4 The administrator of Quality Assurance (Quality Assurance; QA) reports directly to the President. Is responsible for the development, implementation and maintenance of the QA Program and implementing procedures; and conducts the annual review and assessment of the QA Program to advise management of its adequacy and effectiveness. Quality Assurance is also responsible for providing administrative and functional guidance to the Quality personnel; and oversees customer and regulatory audits of the QA Program. Quality Assurance is to be sufficiently independent from the pressures of cost, production, and scheduling when opposed to safety function considerations; has the authority to stop production and delivery; and has sufficient authority, access to work areas, and organizational freedom to:

1.4.1 Identify quality problems;

1.4.2 Initiate, recommend or provide solutions to quality problems through designated channels;

1.4.3 Verify implementation of solutions;

1.4.4 Assure that further processing, delivery, or installation or use is controlled until proper disposition of a nonconformance, deficiency, or unsatisfactory condition has occurred;

1.5 Regulatory Affairs is responsible for assuring the regulatory requirements are met regarding the company's licensing and operating activities of the QA Program for Packages.

1.6 Customer Service is responsible for the assembly of customer contract documents; acts as the liaison between the customer and responsible department managers; the timely review of inquiries and orders; and preparation of procurement documents for materials, items and services in accordance with QA Program requirements.

1.7 Services is responsible for the maintenance and operation of the Packages as required by the QA Program.

1.8 The administrator of Engineering (Engineering) reports directly to the President. Is responsible for execution of the QA Program for licensing and technical matters; for providing technical services and qualified personnel to support projects for Packages in accomplishing the required scope of work; to assure design activities comply with the applicable code, specification or standard requirements; and are responsible for the technical quality of engineering, licensing, fabrication, and design document activities.

1.9 To support the QA Program, subcontract personnel may consist of, but not be limited to Engineering, Quality Assurance, Inspection and Test (I&T), Nondestructive Examination (NDE), or Audit personnel; and are responsible for the completion of quality activities for which they are trained and/or qualified, as required, in the applicable sections of the QA Program and appropriate implementing procedures.

1.10 Any individual designated responsibility in this QA Program may delegate the performance of that responsibility to a qualified individual within their department; but, retains the overall responsibility for ensuring compliance with the requirements of the QA Program.

1.11 The manager or director of a department may perform any of the activities assigned to individuals within their department provided they are qualified to perform the activities.

2.0 QUALITY ASSURANCE PROGRAM

2.1 AOS is responsible for the establishment, planning, implementation and maintenance of the QA Program as it pertains to the design, procurement, fabrication, assembly, inspection, testing, handling, shipping, storing, cleaning, operation, maintenance, repair and modification of Package systems and/or components that are safety-related or important-to-safety; under control of a license, certificate, or application for Certificate of Compliance (CoC) operated by AOS.

2.2 When suppliers are used for performance of activities subject to the requirements of the QA Program, they are qualified by AOS to ensure compliance; however, AOS retains the overall responsibility for the quality of those activities.

2.3 The QA Program is described in detail in this manual; and comprises of all planned and systematic actions to provide adequate confidence that all activities are in accordance with the rules and requirements identified by 10CFR Part 71 Subpart H

2.4 It further provides for the accomplishment of activities affecting quality under controlled conditions, as applicable: utilizing appropriate equipment, special controls, processes, suitable environmental conditions, test equipment, tools, skills, and personnel to attain the required quality, to satisfy established prerequisites for given activities, and for verification of quality by examination, inspection, or test.

2.5 The QA Program is supported by implementing procedures (Standard Operating Procedures – SOP), and appropriate forms and exhibits specifically defining the methods of operation for various processes, controls, and examinations, personnel qualifications important to safety; which establish and implement processes to detect and control quality problems.

2.6 In the case of conflict between an existing instruction or procedure and the QA Program, the QA Program shall prevail; and the instruction or procedure shall be revised.

2.7 To assure the effective implementation of the QA Program a system of planned and periodic documented internal audits and a regular review of the status and adequacy of the QA Program are controlled in accordance with QA Program requirements.

2.8 Revisions to the QA Program shall be tracked and controlled in accordance with the applicable implementing procedures.

2.9 Revisions to the QA Program are subject to review and approval by the U.S. Nuclear Regulatory Commission (USNRC; NRC) prior to implementation. The date of implementation for the QA Program revision is to be after the date of NRC approval; and upon completion of all programmatic requirements (i.e., training, etc.).

2.10 All personnel performing activities affecting quality shall be indoctrinated and trained in accordance with the implementing procedures for their responsibility to the QA Program as they relate to their duties.

2.10.1 Indoctrination and training shall be commensurate with scope, complexity, importance of the activities; and the education, experience, and proficiency of the person.

2.10.2 Records of personnel training and/or qualification shall be established, certified and maintained by Quality Assurance.

2.11 All personnel (including subcontractors) performing specialized activities shall be qualified, when required, in accordance with the appropriate implementing procedures.

2.11.1 Specialized activities may include, but not be limited to: Inspection and Test (I&T) Personnel, Nondestructive Examination (NDE) Personnel, Lead Auditors, and Engineering Personnel.

2.11.2 Indoctrination and training shall be commensurate with scope, complexity, importance of the activities; and the education, experience, and proficiency of the person.

2.11.3 Records of personnel training and/or qualification shall be established, certified and maintained by Quality Assurance.

3.0 DESIGN CONTROL

3.1 Measures are established that assure the applicable regulatory requirements and the Package design for safety-related or important-to-safety activities specified in the license are adhered to; and are described in detail by the implementing procedures. Design control measures are applied as required to assure that the following items are correctly identified, as applicable: criticality physics, radiation shielding, stress, thermal, hydraulic, and accident analyses, compatibility of materials, accessibility for in-service inspection, maintenance and repair, features that facilitate decontamination, and delineation of inspection and test acceptance criteria.

3.1.1 Package design control establishes those measures that ensure all applicable codes, standards, specifications, regulatory requirements, inspection and test criteria, operational and maintenance requirements, handling and storage are correctly translated into specifications, drawings, procedures, and instructions.

3.1.2 Appropriate design codes and standards used in the Package design are specified in the design documents. When such codes and standards are not available, alternate approaches shall be identified in the design documents, and utilized in the formulation of the Package design activities.

3.1.3 It provides for established measures for the inclusion of specified and appropriate quality standards to be included in the design documents, and that deviations from those standards are controlled.

3.1.4 Measures to control material, parts, equipment and processes are established for the selection and review of the suitability of the same; and are essential to the function of the material, parts and components of the packaging that are deemed important to safety.

3.1.5 Design analyses are sufficiently detailed and documented in order that a technically qualified person who is qualified in the subject can review and understand the analyses, to verify the adequacy of the results without recourse to its originator.

3.1.6 Computer programs that are used for design analysis or verification are controlled in accordance with the implementing procedures; which provide for verification of the accuracy of the computer results and to assess and resolve reported computer program errors.

3.2 The implementing procedures identify and control the design interfaces and coordinates between participating design organizations.

3.3 All design documents (i.e., specifications, calculations, drawings, procedures, and instructions) are reviewed to verify the adequacy of the design and approved by designated individuals or groups other than those responsible for the original design using specified methods. Verification methods used to assure design adequacy may be one or more of the following: design reviews, alternate calculations, or qualification testing.

3.4 In the event that a testing program is used to verify the adequacy of the design, the conditions and requirements are specified.

3.5 When design control changes are necessitated, the same design control measures used for the revision are subject to the same controls utilized for the original design. Changes that affect the approved design conditions established by the regulatory authority are submitted for approval as required prior to implementation.

3.6 Control of design documents and revisions are handled in accordance with QA Program requirements.

4.0 PROCUREMENT DOCUMENT CONTROL

4.1 Provisions and control of procurement documents have been established to ensure that all safety-related or important-to-safety, and quality assurance requirements are identified in the appropriate procurement documents; and are described in detail by the implementing procedures.

4.2 Procurement documents shall contain reference to, as required: scope of work, technical requirements, applicable regulatory requirements, material identification requirements, drawings, specifications, codes and standards, special process instructions, inspection and test requirements, supplier (and pass-on to sub-supplier) quality assurance program requirements, right of access, documentation, and nonconformance requirements.

4.3 Documentation required by the supplier to perform activities affecting quality (e.g., drawings, specifications, procedures, fabrication and inspection plans, inspection and test records, personnel and procedure qualifications, results of chemical and physical tests on material) are to be prepared, maintained and submitted for approval.

4.4 Procurement documents are reviewed and approved by Engineering and Quality Assurance, as required, prior to issuance.

4.5 Procurement of replacement parts required for the packaging that are important to safety are subject to the same control as the original parts; including designation of supplier status, technical and QA requirements; and approval of the procurement documents prior to issuance.

4.6 Changes made to procurement documents are subject to the same control as the original document. The originating organization prepares the change, with a change order or revision indicator and date; and presents to the responsible person for review and approval.

5.0 INSTRUCTIONS, PROCEDURES, AND DRAWINGS

5.1 Measures have been established to assure that all safety-related or important-to-safety activities that affect quality are performed in accordance with this QA Program are done using documents that include pertinent information for activities affecting quality. This information is disseminated in the form of instructions, procedures, and drawings, to describe the activity required with a level of detail commensurate with the complexity of the activity, and the need to assure consistent and acceptable results; and are described in detail by the implementing procedures.

5.2 Compliance with the approved instructions, procedures and drawings is mandatory to all personnel that perform safety-related or important-to-safety activities that affect quality.

5.3 The instructions or procedures include or reference the appropriate quantitative and/or qualitative acceptance criteria to determine that prescribed results have been attained.

5.4 The documents are to describe the required activity in a level of detail that is appropriate to the following considerations: the complexity of the task, significance of the item or activity, work environment, and worker proficiency and capability.

5.5 Documents provided to suppliers for the completion of the procurement of material, items or services are identified in the procurement documents or associated specifications.

6.0 DOCUMENT CONTROL

6.1 Requirements are provided for the preparation, issuance and change of documents that prescribe safety-related or important-to-safety activities that affect quality, and are controlled to assure that the correct documents are being employed; and this is described in detail by the implementing procedures.

6.2 Controlled documents may include, but are not limited to:

- 6.2.1 Design and fabrication specifications
- 6.2.2 Design and fabrication drawings
- 6.2.3 Special process specifications and procedures
- 6.2.4 Inspection and Test procedures
- 6.2.5 QA Program and implementing procedures
- 6.2.6 Operational test procedures and data

6.3 Documents that prescribe safety-related or important-to-safety activities that affect quality are reviewed and approved for technical adequacy, completeness, and incorporation of appropriate quality requirements prior to acceptance and issuance.

6.4 Document Control reports to the administrator of Quality Assurance; and is responsible for the execution of the company document control procedures, measures to assure only current documents are in use, and document storage, as a function of the QA Program.

6.5 Changes made to documents are subject to the same control as the original document in accordance with the applicable implementing procedures. The originating organization prepares the change, with a revision indicator and date; and presents to the responsible person or organization for review and approval.

7.0 CONTROL OF PURCHASED MATERIAL, EQUIPMENT AND SERVICES

7.1 Provisions have been established for documentation and control of material, equipment and services for safety-related or important-to-safety activities affecting quality when purchased either directly or through contractors or subcontractors, and to assure conformance to the established procurement documents; and are described in detail by the implementing procedures.

7.2 During the design process Engineering designates specific safety classifications to items which affect material procurement; and is defined in the implementing procedures.

7.3 The selection of a supplier's capability, source evaluation and control, and objective evidence of quality, shall be determined prior to the issuance of an order. Approved suppliers are listed on the Approved Suppliers List (ASL) for the items or services provided.

7.4 Suppliers designated to provide items and/or services are controlled by the conduct of an audit/survey to determine supplier approval; which are performed by qualified personnel and documented as QA Records; and are based on one or more of the following criteria:

7.4.1 Compliance with the established requirements of 10CFR Part 71 Subpart H; 10CFR Part 50 Appendix B; ASME Section III, or other codes, standards, or specifications that are applicable to the scope of work to be performed.

7.4.2 Review of previous records to establish the supplier's past performance.

7.4.3 Survey of the supplier's facilities and review of the supplier's QA Program to assess and verify the adequacy and implementation of quality controls consistent with those requirements invoked.

The effectiveness and control of quality performed by suppliers, contractors or subcontractors are to be assessed and documented by QA at intervals that are consistent with the importance, complexity and quantity of the product described.

7.5 Suppliers are required to submit documentary and objective evidence required to complete activities affecting quality (e.g., drawings, specifications, procedures, fabrication and inspection plans, inspection and test records, personnel and procedure qualifications, results of chemical and physical tests on material) for review and approval to verify conformance to procurement documents. For procurement conditions not met by the suppliers, documentation is to be submitted for review and approval, to assure the technical and quality requirements have not been compromised.

7.6 Consideration regarding source verification and receiving inspection verification are to be consistent with the importance and complexity of the delivered material, equipment and services; and is described in detail by the implementing procedures.

7.7 When consultants are used in the performance of organizational responsibilities subject to the requirements of the QA Program, their requisite ability is determined by AOS to ensure compliance; the personnel are authorized by AOS to work under the QA Program; and verification of quality requirements is accomplished through internal audits.

7.8 Material furnished by the customer is to be controlled in accordance with the requirements of the QA Program. When required, the customer shall furnish material certification for job compliance review and inclusion with the job records. The material is to be receipt inspected in the same manner as for material procured by AOS. This material shall only be used for its intended customer and designated purpose.

7.9 When post-installation testing is required, post-installation test requirements and acceptance documentation shall be established by AOS, with technical input furnished by the supplier, as required.

7.10 When services are subcontracted (e.g., engineering, auditing, calibration, etc.) a verification of the technical data received shall be completed and objective evidence reviewed for conformance with the purchase document requirements. When the performance of the service warrants, surveillance and/or audit of the activity is to be considered. For calibration, the supplier's calibration results shall be controlled in accordance with the implementing procedures.

7.11 When dedication of commercial grade items or services is required, it shall be controlled in accordance with the implementing procedures.

7.12 Nonconformances identified are to be controlled in accordance with QA Program requirements.

8.0 IDENTIFICATION AND CONTROL OF MATERIALS, PARTS, AND COMPONENTS

8.1 Methods and controls have been established to assure that all material, parts, and components to be used or installed for fabrication, assembly, maintenance and repair activities that are safety-related or important-to-safety have been correctly identified and controlled; and are described in detail by the implementing procedures.

8.2 Traceability is assured by the maintenance of heat/lot numbers, part numbers, serial numbers or other appropriate means; and the traceability is recorded physically on the item or in records maintaining traceability to the item.

8.3 These controls are also to assure the prevention of the use of incorrect or defective material, parts, or components in the items; and for those that have not received the required examinations, tests, or inspections.

8.4 Identification marks used shall be applied using methods and materials, which are legible and not detrimental to the item involved; and shall be located in areas not affecting or interfering with the function or quality aspects of the item. Identification marks used during storage of items shall be controlled; with provisions for maintenance or replacement due to damage from handling, aging, or environmental exposure.

8.5 Material determined to have a shelf-life or limited-life shall be controlled in accordance with the requirements of the implementing procedures.

8.6 Records of identification and control of materials, parts, or components are to be maintained in accordance with QA Program requirements.

9.0 CONTROL OF SPECIAL PROCESSES

9.1 Controls have been established to assure that special processes performed by AOS or its approved suppliers, contractors, or subcontractors that are safety-related or important-to-safety are accomplished in accordance with specified requirements; and are described in detail by the implementing procedures.

9.2 Special processes include, but are not limited to, welding, heat treating, nondestructive examination, destructive testing; and are to be controlled and accomplished by qualified personnel using qualified procedures, including appropriate acceptance criteria, as required.

9.3 Special processes are to be completed in accordance with the applicable codes, standards, specifications, criteria, or other special requirements defined by project requirements and the QA Program. When special processes are not covered or where specified quality requirements exceed those of the existing codes and standards, the necessary requirements for personnel qualifications, procedures, or equipment are specified or referenced in procedures or instructions.

9.4 Adherence to the approved procedures and processes in executing special processes is the responsibility of the organization performing the same.

9.5 Records of all special process activities, procedures and personnel qualifications are to be maintained in accordance with QA Program requirements.

10.0 INSPECTION

10.1 A program has been established for the inspection of safety-related or important-to-safety activities that affect quality, for the verification of conformance to documented drawings, instructions and procedures used for accomplishing the activity, and to provide for the timely identification, disposition, and recommended corrective action of nonconforming conditions; and is described in detail by the implementing procedures.

10.2 Inspections are to be performed by qualified personnel other than those who perform or directly supervise the work being inspected. Inspection personnel shall meet the requirements specified in QA Program requirements.

10.3 Inspection or surveillance, or indirect control by process monitoring methods shall be completed, as required; with both inspection and process monitoring being done when control of the inspection is inadequate without both.

10.4 Inspections are to be performed to written procedures controlled in accordance with QA Program requirements; and the results are to be documented.

10.5 Mandatory hold points of inspection activities shall be designated and documented accordingly. Work beyond a Hold Point shall not proceed without the approval of the organization assigning the Hold Point; or consent to waive the specified hold point shall be recorded.

10.6 M&TE shall be selected to assure calibration status and of proper type, range, and accuracy to accomplish the inspection.

10.7 Records of inspections shall be completed, maintained and stored in accordance with QA Program requirements.

11.0 TEST CONTROL

11.1 A program has been established for the performance of safety-related or important-to-safety tests required to demonstrate that structures, systems and components will perform satisfactorily in service, and to provide for the timely identification, disposition, and recommended corrective action of nonconforming conditions; and is described in detail by the implementing procedures.

11.2 Inspections are to be performed by qualified personnel other than those who perform or directly supervise the work being tested. Test personnel shall meet the requirements specified in QA Program requirements.

11.3 Direct or indirect (process monitoring) inspection methods shall be completed as required. Testing or surveillance, or indirect control by process monitoring methods shall be completed, as required; with both test and process monitoring being done when control of the test is inadequate without both.

11.4 Testing requirements are to be performed to written procedures controlled in accordance with QA Program requirements; and the results are to be documented.

11.5 Mandatory hold points of test activities shall be designated and documented accordingly. Work beyond a Hold Point shall not proceed without the approval of the organization assigning the Hold Point; or consent to waive the specified hold point shall be recorded.

11.6 Test procedures are to specify provisions assuring that all prerequisites for the test have been met, adequate test instrumentation is available and used, and the testing is performed under suitable environmental conditions.

11.7 M&TE shall be selected to assure calibration status and of proper type, range, and accuracy to accomplish the test.

11.8 Test control for computer programs are in accordance with the implementing procedures.

11.9 Records of tests shall be completed, maintained and stored in accordance with QA Program requirements.

12.0 CONTROL OF MEASURING AND TEST EQUIPMENT

12.1 Methods have been established for the identification, control, calibration and selection of Measurement and Test Equipment (M&TE) used in safety-related or important-to-safety activities affecting quality; and are described in detail by the implementing procedures.

12.2 All M&TE used shall be calibrated periodically and at scheduled intervals, or whenever the accuracy of the M&TE is suspect to assure acceptable accuracy to the stated requirements. Calibration methods and intervals shall be based on the type of equipment, stability characteristics, required accuracy, intended use, and other conditions affecting performance.

12.2.1 Calibration is to be done using certified master standards having known relationship to nationally recognized standards, where such standards exist. Where none exist, the manufacturer's recommended standard shall be documented and used.

12.2.2 Calibration of M&TE is to be performed by properly trained personnel, or by qualified suppliers.

12.2.3 Control of M&TE shall be done using unique equipment serial numbers, records, and calibration status indicators.

12.2.4 Calibration of M&TE shall be completed in accordance with written instructions or procedures which include the requirements for methods, tolerances and calibration intervals.

12.3 If M&TE is determined to be out-of-calibration, an evaluation is performed and documented to determine the validity of inspections or tests performed, and to determine the acceptability of items inspected or tested since the last acceptable calibration. This is to be controlled in accordance with QA Program requirements.

12.4 Commercial equipment such as rulers, tape measures, levels, etc. do not require calibration and control measures when normal commercial practices provide the required accuracy.

12.5 Records of calibration are to be completed, maintained and stored in accordance with QA Program requirements.

13.0 HANDLING, STORAGE AND SHIPPING

13.1 Methods have been established for the control of items in order to prevent damage, deterioration, or loss during all phases of safety-related or important-to-safety activities affecting quality; and are described in detail by the implementing procedures.

13.2 Special handling, storage and shipping requirements for a project are to be performed in accordance with written procedures; which shall address the need for special coverings, special equipment and tools, marking and labeling that is used to adequately maintain and preserve items, or indication of the presence of special environments or the need for special controls, as required.

13.3 Personnel performing special handling and lifting operations with equipment are to be experienced and trained in the use of said equipment.

14.0 INSPECTION, TEST AND OPERATING STATUS

14.1 Methods are provided for determining the status of safety-related or important-to-safety inspection and test activities; and are described in detail by the implementing procedures.

14.2 Procedures are established and identify and provide as applicable: criteria, procedure, equipment, personnel qualifications, acceptance criteria, and control documentation.

14.3 Procedures provide for means of identification through the use of stamps, tags, labels, or other suitable methods.

14.4 The status of nonconformances is to be controlled in accordance with QA Program requirements.

15.0 NONCONFORMING MATERIALS, PARTS, AND COMPONENTS

15.1 Provisions have been established for preventing items and activities that do not conform to specified requirements from inadvertent installation or use. Controls provide for the identification, documentation, evaluation, segregation (when practical), disposition, and proper notification to affected organizations; and are described in detail by the implementing procedures.

15.2 Nonconformances are to be documented in writing on a Nonconformance (NCR) Report; and presented to appropriate organizations for review, acceptance and disposition.

15.3 Nonconforming items are to be identified and segregated, when practical, to prevent the inadvertent installation or use until properly dispositioned. Identification is by tagging, marking or other methods that do not adversely affect the end use of the item; and shall be legible and easily recognizable.

15.4 Dispositions of the nonconformance shall be: Accept-As-Is, Repair, Rework or Reject/Scrap/Return to Supplier.

15.4.1 Technical justification and independent verification to assure compliance with the design, regulatory and contractual requirements for the acceptance of a "repair" or "use-as-is" disposition shall be documented.

15.4.2 Items dispositioned as "Repair" or "rework" are to be completed and controlled, and verified by re-inspection or re-testing to the original acceptance criteria, as required by documented and approved methods; unless the disposition established an alternate acceptance criteria.

15.5 Dispositions shall in no way negate regulatory, code, specification, design, or technical requirements.

15.6 Nonconformances and associated work is to be completed and accepted prior to closure.

15.7 Nonconformance reports and associated documentation are to be maintained in accordance with QA Program requirements.

15.8 In complying with the requirements of the quality assurance criteria document specified, the applicable provisions of 10CFR21 - Reporting of Defects and Noncompliances shall be controlled in accordance with the implementing procedures.

16.0 CORRECTIVE ACTION

16.1 Methods have been established for the prompt identification and correction of conditions adverse to quality and corrected as soon as practical; and are described in detail by the implementing procedures.

16.2 The identification of a significant condition adverse to quality, the cause of the condition, and the corrective actions taken shall be documented; and are reported to the appropriate levels of management.

16.3 Completed corrective and preventive actions are to be verified prior to closure.

16.4 Corrective Actions are to be documented in writing on a Corrective and Preventive Action (CAPA) Report; and presented to the responsible organization for determination of action and response. Corrective actions shall in no way negate regulatory, code, specification, design, or technical requirements.

16.5 Corrective actions, associated work and objective evidence is to be completed and accepted prior to closure.

16.6 Corrective and Preventive Action reports and associated documentation are to be maintained in accordance with QA Program requirements.

17.0 QUALITY ASSURANCE RECORDS

17.1 Documentary evidence has been provided for safety-related or important-to-safety items and activities completed that affect quality, and that meet the specified quality requirements. QA records shall be identified, generated, authenticated, and maintained; and their final disposition specified. These requirements are described in detail by the implementing procedures.

17.2 Records are to be specified in the appropriate documents, as required; e.g., design specifications, procurement documents, test and operational procedures. They are to be legible, accurate and traceable to the associated items and activities; and shall be authenticated.

17.3 QA records are identified and retained as Lifetime or Non-Permanent records by AOS or its customers, as appropriate. Records are identified, indexed, stored, and maintained in accessible locations.

17.4 In addition to the requirements in the implementing procedures, any other applicable regulatory requirements must be adhered to.

18.0 AUDITS

18.1 A system has been established for conducting audits of company and supplier safety-related or important-to-safety activities that affect quality, to verify compliance with all applicable regulations, codes and standards; and to determine their effectiveness and compliance with the appropriate QA Program. These requirements are described in detail by the implementing procedures.

18.2 Planned and periodic audits of all aspects of the QA Program and supplier's quality programs shall be conducted in accordance with pre-determined schedules, and supplemented with additional audits or surveillances, when necessary. All applicable elements of the QA Program are audited at least once each year.

18.3 Appropriately trained personnel shall meet the requirements specified in the QA Program requirements; and shall not have direct responsibility in the area being audited.

18.4 Audits are established by developing an audit plan; to identify the personnel, scope, requirements, and applicable documentation.

18.5 Audits are conducted using written checklists; and are to provide sufficient objective evidence to determine effective implementation and effectiveness. The audit is to include an evaluation of the results of previous QA Program audits and results of audits from other sources; and significant changes in personnel, the organization, or the QA Program.

18.6 An audit report is completed and includes identification of the objective evidence established and recorded, and the effectiveness of implementation. The results of the audits are reported to the appropriate level(s) of management for the area(s) audited.

18.7 Corrective actions resulting from audits are undertaken by responsible management; schedules are established, and results are verified for implementation and closure; and to determine the necessity for performance of appropriate follow-up, including re-audit of deficient areas, when necessary.

19.0 REFERENCES

The following referenced documents are integral, in whole or in part, as a basis for the QA Program. This QA Program meets the latest edition/revision of the referenced documents, unless otherwise identified in any of the corresponding documents or as identified below.

19.1 10CFR Part 21, Code of Federal Regulations, Title 10 – Reporting of Defects and Noncompliance

19.2 10CFR Part 50 Appendix B, Code of Federal Regulations – Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants

19.3 10CFR Part 71 Subpart H, Code of Federal Regulations – Packaging and Transportation of Radioactive Material, Quality Assurance

19.4 USNRC Regulatory Guide 1.28 – Quality Assurance Program Requirements (Design and Construction)

19.5 USNRC Regulatory Guide 7.10 – Establishing Quality Assurance Programs for Packaging Used In The Transport of Radioactive Material

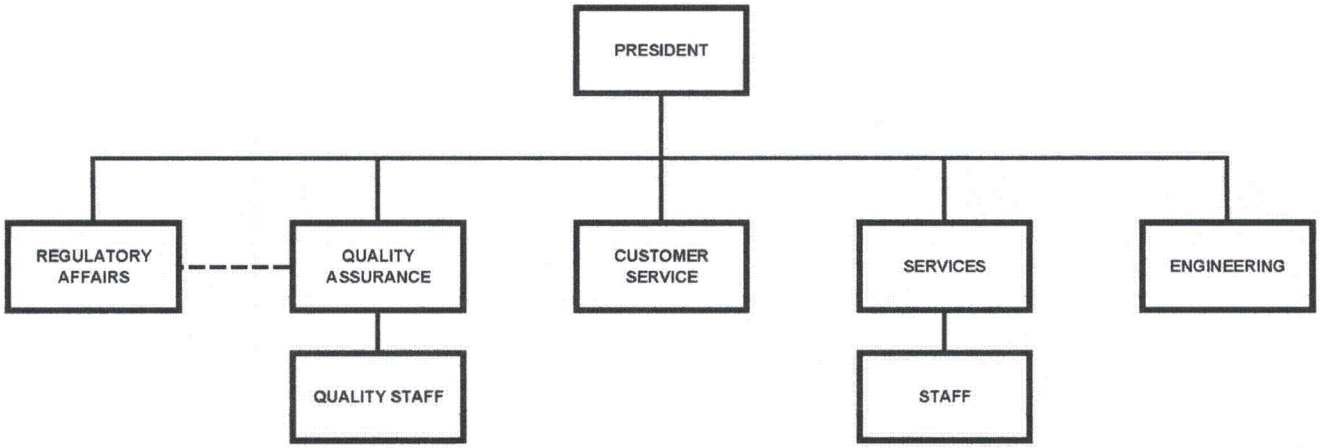
19.6 NUREG/CR-6407, February 1996 – Classification of Transportation Packaging and Dry Spent Fuel Storage System Components According to Importance to Safety

19.7 ASME NQA-1 – Quality Assurance Requirements for Nuclear Facility Applications

19.8 ANSI N45.2 – Quality Assurance Program Requirements for Nuclear Facilities (and associated daughter standards as they apply to packaging activities)

19.9 IAEA Safety Requirements No. TS-R-1 (2005 Edition), Regulations for the Safe Transport of Radioactive Material

19.10 IAEA Safety Guide No. TS-G-1.1 (ST-2), Appendix IV - Advisory Material for the IAEA Regulations for the Safe Transport of Radioactive Materials, Quality Assurance in the Safe Transport of Radioactive Material

20.0 ORGANIZATIONAL CHART

The AOS organizational structure for the QA Program supporting Radioactive Material Transport Packages: